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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/214,478	06/07/99	BRANTON	P 50013/002003

KRISTINA BIEKER BRADY  
CLARK & ELBING  
176 FEDERAL STREET  
BOSTON MA 02110

HM12/0929

EXAMINER

CHEN, S

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

09/29/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trad marks**

## Office Action Summary

Application No.

09/214,478

Applicant(s)

Branton et al.

Examiner

Shin-Lin Chen

Group Art Unit

1633

☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire \_\_\_\_\_ thirty days, \_\_\_\_\_ from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claim

☒ Claim(s) 1-60 and 64-80 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☐ Claim(s) \_\_\_\_\_ is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☒ Claims 1-60 and 64-80 are subject to restriction or election requirement.

### Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1633

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 5-7, 21, 22, 25-27, 41-44, 69, 70 and 78-80, drawn to a method of increasing apoptosis in a cell by using an E4orf6 polypeptide or apoptotic fragment thereof, or both E4orf6 and E4orf4 polypeptides, and a pharmaceutical composition comprising an E4orf6 polypeptide, an apoptotic fragment thereof, or both E4orf6 and E4orf4 polypeptides for the treatment of human diseases involving inappropriate cell survival.

Group II, claim(s) 3, 7, 8, 23, 27, 28 and 30-40, drawn to a method of increasing apoptosis in a mammal by using a transgene encoding an apoptotic E4orf6 polypeptide or an apoptotic fragment thereof, and a pharmaceutical composition comprising nucleic acid encoding an E4orf6 polypeptide and a pharmaceutical acceptable carrier.

Group III, claim(s) 4-10, 14-20, 24-27, 29 and 30, drawn to a method of increasing apoptosis in a cell by using a compound which increases E4orf6 mediated E4orf6 biological activity, or using a first compound which increases E4orf6 mediated E4orf6 biological activity and a second compound which increases E4orf6 mediated E4orf4 activity.

Group IV, claim(s) 11, 12, 15-18, 21, 22, 25-27, 55-58, 72, 73 and 78-80, drawn to a method of increasing apoptosis in a cell by using an E4orf4 polypeptide or an apoptotic fragment

Art Unit: 1633

thereof, or both E4orf4 and E4orf6 polypeptides, and a pharmaceutical composition comprising E4orf4 polypeptide, an analog or fragment thereof, or both E4orf4 and E4orf6 polypeptides for the treatment of human diseases involving inappropriate cell survival.

Group V, claim(s) 13, 17, 18, 23, 27, 28, and 45-54,, drawn to a method of increasing apoptosis in a mammal by using a transgene encoding an apoptotic E4orf4 polypeptide or an apoptotic fragment thereof, and a pharmaceutical composition comprising a nucleic acid encoding an E4orf4 polypeptide or an apoptotic fragment thereof..

Group VI, claim(s) 59, 60 and 64-68, drawn to a method for identifying a compound as an E4orf6 or E4orf4 analog by using a cell expressing the adenovirus E1A-289R protein or a cell expressing protein phosphatase 2A.

Group VII, claim(s) 71, drawn to a pharmaceutical composition comprising a compound which induces apoptosis or other cytotoxic effects analogous to E4orf6 biological activity for the treatment of human diseases involving inappropriate cell survival.

Group VIII, claim(s) 74-77, drawn to a pharmaceutical composition comprising a compound which induces protein phosphatase 2a, or induces apoptosis or other cytotoxic effects analogous to E4orf4 biological activity for the treatment of human diseases involving inappropriate cell survival.

Claims 5, 6 are generic to groups I and III. Claim 7 is generic to groups I-III. Claims 25 and 26 are generic to groups I, III and IV. Claim 27 is generic to groups I-V. Claims 15-17 are generic to groups III and IV. Claim 18 is generic to groups III-V. Claims 21, 22 and 78-80 are

Art Unit: 1633

generic to groups I and IV. Claim 28 is generic to groups II and V. Claim 30 is generic to groups II and III. Note that generic claims will be examined only to the extent that they read on the elected subject matter upon election. Further, and upon election, the generic claims must be amended to read on the elected invention, since if found allowable, they would improperly contain non-elected subject matter.

2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-III are drawn to a method using different compositions having different chemical structure, physical properties and biological function: transgene, polypeptide, and a compound other than a transgene and a polypeptide. They are different products that are used in different methods for different purposes. Further, Chroboczek et al, 1996 (U) discloses a nucleotide sequence, GenEmbl Accession No. M73260, which is 100% identical to SEQ ID No. 1 and SEQ ID No. 3. Herisse et al., 1982 (V) discloses a polypeptide sequence, PIR\_63 Accession No. A03805, which is 100% identical to SEQ ID No. 2. Thus, groups I-III do not share special technical features and do not relate to a single general inventive concept under PCT Rule 13.1.

Groups IV, V and VIII are drawn to different pharmaceutical compositions having different chemical structure, physical properties and biological function: nucleic acid, polypeptide, and a compound other than a nucleic acid and a polypeptide. They are different

Art Unit: 1633

products that are used in different methods with different method steps and doses. Thus, groups IV, V and VIII do not share special technical features and do not relate to a single general inventive concept under PCT Rule 13.1.

Groups I-III and IV, V, VIII are drawn to different adenoviral gene encoding different adenoviral protein, E4orf6 and E4orf4, which differ chemically, structurally and biologically. Thus, they do not share special technical features and do not relate to a single general inventive concept under PCT Rule 13.1.

Groups VI and I-V, VII, VIII are drawn to different methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. Thus, groups VI and I-V, VII, VIII do not share special technical features and do not relate to a single general inventive concept under PCT Rule 13.1. Similarly, groups VII and I-VI, VIII do not share special technical features and do not relate to a single general inventive concept under PCT Rule 13.1.

3. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any


Art Unit: 1633

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703) 308-0447. The fax phone number for this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

  
**DEBORAH J.R. CLARK**  
**PRIMARY EXAMINER**

Shin-Lin Chen, Ph.D.